UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC., Plaintiffs, v. LIVE OAK HHI, LLC, Defendant.	Case No. 9:25-cv-00441-DCN

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk") file their complaint against Live Oak HHI, LLC ("Defendant") for false advertising and unfair and deceptive trade practices, and seek injunctive and other relief. Plaintiffs allege as follows, on actual knowledge with respect to themselves and their own acts, and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.

4. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic®, Wegovy®, and Rybelsus®.

5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that claimed that their Unapproved Products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic and Wegovy are currently the only "two injectable semaglutide products FDA-approved for the U.S. market."[1]

6. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, related state laws, and the common law arising out of Defendant's acts of false advertising and unfair and deceptive trade practices.

7. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide.

8. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk's FDA-approved semaglutide medicines.

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

[1] U.S. FOOD & DRUG ADMIN., WARNING LETTER TO OZEMPEN.COM, MARCS-CMS 684435 (June 24, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024.

THE PARTIES

10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

11. Novo Nordisk developed the Ozempic®, Wegovy®, and Rybelsus® medicines.

12. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic®, Wegovy®, and Rybelsus® medicines in the United States.

13. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.

14. NNI promotes, offers, and sells Novo Nordisk's Ozempic®, Wegovy®, and Rybelsus® medicines throughout the United States, including in this District.

15. Defendant Live Oak HHI, LLC is a South Carolina limited liability company with a business address at 90 Main Street, Hilton Head Island, South Carolina 29926, and a registered agent address at 47 Shelter Cove Lane, Hilton Head Island, South Carolina 29928, in this judicial district.

16. Defendant sells and promotes compounded drug products that purport to contain semaglutide, but that have not been approved by the FDA ("Unapproved Compounded Drugs").

17. Defendant falsely claims or otherwise misleadingly suggests that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic®, Wegovy®, and Rybelsus® medicines.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

19. The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

20. Defendant is subject to personal jurisdiction in this District because Defendant is a South Carolina limited liability company and has a principal place of business in this District.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC®, WEGOVY®, AND RYBELSUS® TRADEMARKS

22. Plaintiffs use the trademarks "Ozempic," "Wegovy," and "Rybelsus" to identify and promote the FDA-approved Ozempic®, Wegovy®, and Rybelsus® medicines. The Ozempic®, Wegovy®, and Rybelsus® medicines are sold and marketed in the United States by NNAS's indirect, wholly-owned subsidiary, NNI.

23. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. The Ozempic® medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

24. The Wegovy® medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged twelve years and older with obesity, and some adults who are overweight and have weight-related medical problems, along with a reduced calorie diet and increased physical activity.

25. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as "cardiovascular" death, heart attack, or stroke in adults with known heart disease and who are either obese or overweight.

26. The Rybelsus® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

27. The Ozempic®, Wegovy®, and Rybelsus® medicines have been extensively studied in clinical trials and are FDA-approved.

28. Each of the Ozempic®, Wegovy®, and Rybelsus® medicines has a unique safety and efficacy profile which is set forth in its respective product label.

29. The Ozempic®, Wegovy®, and Rybelsus® medicines are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

30. Novo Nordisk has never sold its FDA-approved semaglutide medicines, Ozempic®, Wegovy®, and Rybelsus®, to Defendant for resale or redistribution.

31. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

32. The FDA has not approved Defendant's purported semaglutide products.

33. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

34. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[2]

[2] U.S. FOOD & DRUG ADMIN., HUMAN DRUG COMPOUNDING (2024),

35. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."[3]

36. The FDA has further stated that it "does not verify the safety, effectiveness or quality of compounded drugs before they are marketed."[4] "Unnecessary use of compounded drugs may expose patients to potentially serious health risks."[5]

37. As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[6]

38. The process used to produce most "semaglutide" used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk's FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded "semaglutide," however, uses a "semaglutide" manufactured via chemical synthesis. The chemical synthesis process, which is not used for the semaglutide in any FDA-approved semaglutide medicines, has resulted in new

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https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

[3] U.S. FOOD & DRUG ADMIN., COMPOUNDING LAWS AND POLICIES (2020), https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

[4] U.S. FOOD & DRUG ADMIN., COMPOUNDING AND THE FDA: QUESTIONS AND ANSWERS (2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[5] *Id.*

[6] U.S. FOOD & DRUG ADMIN., FDA ALERTS HEALTH CARE PROVIDERS, COMPOUNDERS AND PATIENTS OF DOSING ERRORS ASSOCIATED WITH COMPOUNDED INJECTABLE SEMAGLUTIDE PRODUCTS (2024), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded "semaglutide."[7]

39. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.[8] In several instances, patients mistakenly administered five to twenty times more than the intended dose of compounded "semaglutide."[9]

40. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

41. A previous publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded "semaglutide" up to ten times greater than the intended amount.[10]

42. FDA has issued guidance on its "Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," which provides that: (1) "compounded drugs are not FDA approved"; (2) use of compounded drugs containing "semaglutide" "can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality"; and (3) "FDA has received reports of adverse events related to compounded versions of semaglutide . . . . However, federal law does not require state-licensed pharmacies that are not outsourcing

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[7] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs*, PHARM. RSCH., Oct. 2024, available at https://pubmed.ncbi.nlm.nih.gov/39379664/.
[8] *See* U.S. FOOD & DRUG ADMIN., *supra* note 6.
[9] *Id.*
[10] Joseph E. Lambson et al., *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. AM. PHARMACISTS ASS'N 5 (2023), available at https://www.japha.org/article/S1544-3191(23)00231-5/abstract.

facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported."[11]

DEFENDANT'S FALSE ADVERTISING IN CONNECTION WITH ITS SALE OF UNAPPROVED COMPOUNDED DRUGS

43. Despite the foregoing, Defendant has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

44. Defendant has falsely advertised its Unapproved Compounded Drugs by making statements that describe the Ozempic®, Wegovy®, and Rybelsus® medicines but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

45. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

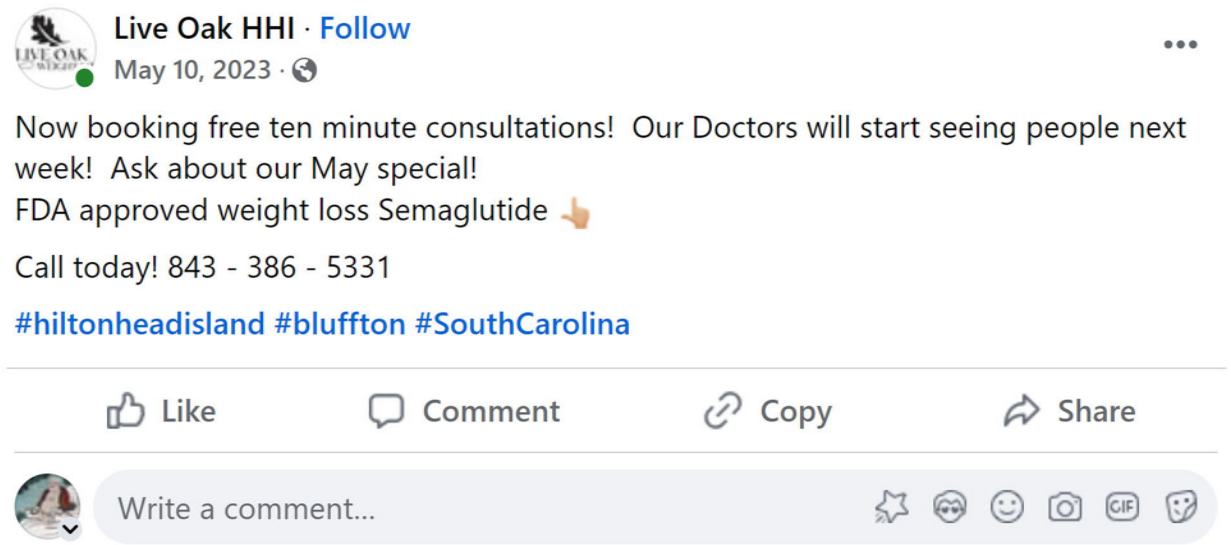
46. On its website, Defendant makes false and misleading representations regarding approval by the FDA.

47. As shown below, Defendant has stated: "Clinical trials by the U.S. Food & Drug Administration showed patients on this amazing drug lose an average ~ 15% of their body weight or ~ 35lbs, but with longer-term yields showed results in a weight loss of 30%." *See* **Exhibit A**.

[11] U.S. FOOD & DRUG ADMIN., FDA'S CONCERNS WITH UNAPPROVED GLP-1 DRUGS USED FOR WEIGHT LOSS (2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

48. Defendant has also made similarly false and misleading representations in promotional posts on social media, including on the Facebook platform.

49. As shown below, Defendant has stated that its purported "semaglutide" products are: "FDA approved." *See* **Exhibit A**.[12]



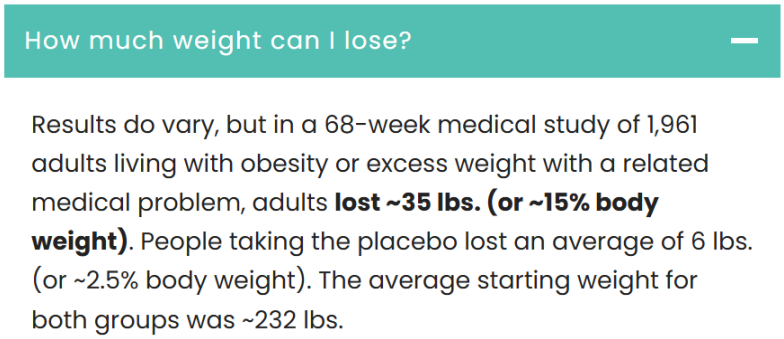
50. Contrary to Defendant's representations, the FDA has made no such approval for Defendant's Unapproved Compounded Drugs or "semaglutide." Instead, the FDA has approved three of Novo Nordisk's medicines which contain semaglutide for the specific indications outlined in the preceding paragraphs.

51. Defendant's false representations mislead customers into believing, incorrectly, that the product with "semaglutide" that Defendant offers has been reviewed and approved by the FDA for safety and effectiveness.

[12] *See also* Live Oak HHI, FACEBOOK, https://www.facebook.com/share/p/19UR1FtiQ3/ (last visited Jan. 2, 2025).

52. Defendant also falsely claims or implies that its Unapproved Compounded Drugs have been subjected to clinical studies and trials, or have otherwise achieved therapeutic outcomes attributable to the Wegovy®, Ozempic®, and Rybelsus® medicines.

53. On its website, as shown below, Defendant in promotional materials refers to studies that on information and belief did not involve the Unapproved Compounded Drugs sold by Defendant: "[I]n a 68-week medical study of 1,961 adults living with obesity or excess weight with a related medical problem, adults **lost ~ 35 lbs. (or ~ 15% body weight)**. People taking the placebo lost an average of 6 lbs. (or ~2.5% body weight). The average starting weight for both groups was ~232 lbs." *See* **Exhibit B**.



54. On information and belief, Defendant has not conducted any placebo-controlled studies on its Unapproved Compounded Drugs and is instead misleadingly referring to studies of Novo Nordisk's FDA-approved medicines to promote its Unapproved Compounded Drugs.

55. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.

56. Defendant's false and misleading statements and practices are likely to cause mistake and deception in the marketplace.

57. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's

FDA-approved medicines, or equivalents thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.[13]

58. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products in violation of Plaintiffs' rights.

59. On information and belief, unless enjoined by this Court, Defendant's conduct will continue to cause mistake and deception.

FIRST CAUSE OF ACTION

Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

60. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

61. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

62. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

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[13] *See, e.g.*, Charlotte Huffman & Mark Smith, *Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs*, WFAA (Feb. 9, 2019), https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested"); U.S. FOOD & DRUG ADMIN., *supra* note 6 ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.").

63. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or who Defendant is trying to persuade to purchase its drugs) information that makes false or misleading statements, including those described herein and in the exhibits hereto.

64. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

65. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

66. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

67. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

68. Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant.

69. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

70. The above-described acts of Defendant are willful.

71. Accordingly, Plaintiffs are entitled to disgorgement of defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

72. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Deceptive and Unfair Trade Practices in Violation of South Carolina Unfair Trade Practices Act (S.C. Code Section 39-5-20 *et seq.*)

73. Plaintiffs reallege and incorporate by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

74. The above-described acts of Defendant constitute unfair methods of competition, and unfair or deceptive acts or practices in violation of the laws of the State of South Carolina, S.C. Code Section 39-5-20 *et seq.*

75. Defendant has violated the South Carolina Unfair Trade Practices Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

76. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

77. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

78. Due to the above-described acts of Defendant, Plaintiffs have suffered ascertainable loss of money or property by reason of Defendant's unfair methods of competition, entitling them to relief.

79. On information and belief, Defendant's unfair and deceptive acts were employed willfully such that Plaintiffs are entitled to attorney's fees and costs and three times the actual damages sustained by Plaintiffs pursuant to Section 39-5-140.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a); and

   b. Engaged in unfair and deceptive trade practices under the South Carolina Unfair Trade Practices Act.

2. That each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

   a. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:

      i. are, or contain, genuine or authentic Novo Nordisk Ozempic®, Wegovy®, or Rybelsus® medicines;

      ii. are sponsored by or associated with Novo Nordisk;

      iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;

      iv. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;

v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

b. engaging in unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic®, Wegovy®, or Rybelsus® medicines; and

c. engaging in deceptive acts or practices with respect to Novo Nordisk's Ozempic®, Wegovy®, or Rybelsus® medicines.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair competition and that this

monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

7. That the Court award Plaintiffs punitive damages by reason of Defendant's willful unlawful actions.

8. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

9. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

10. That the Court award Plaintiffs the costs of suit incurred herein.

11. That the Court award such other or further relief as the Court may deem just and proper.

Date: January 23, 2025

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